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106TH CONGRESS
1ST SESSION

H. R. 1885

To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation into the United States of certain drugs that have been approved by the Food and Drug Administration.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 1999

Mr. BERRY (for himself, Mr. SANDERS, Mrs. EMERSON, Mr. ROHRABACHER, Mr. ABERCROMBIE, and Mr. LEWIS of Georgia) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for facilitating the importation into the United States of certain drugs that have been approved by the Food and Drug Administration.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''International Prescription Drug Parity Act''.

SEC. 2. FACILITATION OF IMPORTATION OF DRUGS APPROVED BY FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

(1) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(2) by striking ''(d)(1)'' and all that follows through the end of paragraph (2) and inserting the following:

''(d)(1) If a covered drug (as defined in paragraph (3)) is domestically approved and is manufactured in a State and then exported, or is domestically approved and is for commercial distribution manufactured in a foreign establishment registered under section 510, the manufacturer shall, as a condition of maintaining the domestic approval of the drug, comply with the following:

''(A) For each shipment of the drug that is manufactured in compliance with current good manufacturing practice and other standards under section 501, the manufacturer shall maintain a record that identifies the shipment and states the fact of such compliance, without regard to whether the shipment is intended for importation into the United States.

''(B) For each such shipment, the manufacturer shall maintain a record that identifies the shipment and provides the labeling required for the drug pursuant to section 501 and pursuant to the application for domestic approval, without regard to whether the shipment is intended for importation into the United States.

''(C) Upon the request of a person who intends to import into the United States drugs from such shipment (and who meets applicable legal requirements to be an importer of covered drugs), the manufacturer shall provide to the person a copy of each of the records maintained under subparagraphs (A) and (B) with respect to the shipment.

''(2) For the purpose of facilitating the importation into the United States of covered drugs, the Secretary shall by regulation establish the following criteria:

''(A) Criteria regarding the records required in paragraph (1) and the use of the records to demonstrate the domestic approval of the drugs and compliance of the drugs with sections 501 and 502.

''(B) Such criteria regarding the labeling of the drugs as the Secretary determines to be appropriate.

''(C) Criteria regarding the amount of charges that may be imposed by manufacturers of the drugs

for maintaining and providing the records specified in subparagraph (A).

''(3) For purposes of this subsection:

''(A) The term 'covered drug' means a drug that is described in section 503(b) or is composed wholly or partly of insulin.

''(B) The term 'domestically approved', with respect to a drug, means a drug for which an application is approved under section 505, or as applicable, under section 351 of the Public Health Service Act. The term 'domestic approval', with respect to a drug, means approval of an application for a drug under such a section.''.

(b) CONFORMING AMENDMENT.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended in paragraph (5) (as redesignated by subsection (a)(1) of this section) by striking ''paragraph (3)'' each place such term appears and inserting ''paragraph (4)''.

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